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AMBU A/S, AMBU INC., AND AMBU LTD.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD.
and LMA NORTH AMERICA, INC.,

Plaintiffs,

v.

AMBU A/S, AMBU INC., AND AMBU LTD.,

Defendants,

AND RELATED COUNTERCLAIMS.

Case No. 3:07-cv-01988 DMS (NLS)

Jury Trial Demanded

**DEFENDANTS' MOTION FOR PARTIAL
SUMMARY JUDGMENT OF
NON-INFRINGEMENT**

Date: September 25, 2009

Time: 1:30 pm

Courtroom: 10, 2nd Floor

Judge: The Honorable Dana M. Sabraw

I. STATEMENT OF ISSUES PRESENTED

A. Whether the broad, V-shaped stiffener of the accused Ambu AuraFlex product contains a “distal rib,” construed by the Court as a “narrow stiffener or reinforcement,” and thus does not, as a matter of law, infringe claim 3 of U.S. Patent No. 7,156,100 (“the ‘100 patent”).

B. Whether the broad, V-shaped stiffener of the accused Ambu AuraFlex product contains a “longitudinal distal rib,” construed by the Court as a “distal rib running lengthwise,” and thus does not, as a matter of law, infringe claim 4 of the ‘100 patent.

II. INTRODUCTION

The last of the remaining products in this case accused of infringement of the ‘100 patent is Ambu’s AuraFlex™. Ambu did not previously move for summary judgment on this product, as it is a special use product whose construction differs from that of the products found by the Court not to infringe in its June 25, 2009 Order granting partial summary judgment. Dkt. 184. The AuraFlex™ has a highly flexible airway tube, making it useful for surgical procedures where the airway tube must be taped in place in other than the midline position, such as for certain head and neck area surgeries.

Ambu’s AuraFlex™ device does not infringe claims 3 and 4 because it neither has, respectively, a “distal rib” nor a “longitudinal distal rib.” In its Order Construing Patent Claims, Docket No. 171, March 17, 2009 (hereafter “Order”), the Court construed claim 3’s “distal rib” as a “narrow stiffener or reinforcement.” Order at 11. In construing this limitation, the Court held that the “distal rib” must be narrow, and expressly rejected LMA’s argument that the “distal rib” need only be smaller than the portion of the cuff that it stiffens. *Id.* The Court furthermore construed claim 4’s “longitudinal distal rib” as a “distal rib running lengthwise,” i.e. a “narrow stiffener or reinforcement running lengthwise.” *Id.*

The relevant undisputed facts show that the accused cuff reinforcement in the AuraFlex™ is neither narrow nor does it run lengthwise. Rather, the AuraFlex™ has a broad, V-shaped reinforcement whose outer dimension is only slightly smaller than the portion of the cuff being reinforced. The AuraFlex™ thus does not literally infringe claims 3 or 4 of the ‘100 patent.

LMA cannot resort to the doctrine of equivalents to satisfy the missing “distal rib” or

1 “longitudinal distal rib” elements missing from the AuraFlex™. There can be no infringement
2 under the doctrine of equivalents where, as here, in order to reach the accused product, the patent
3 holder would have to read a claim limitation entirely out of the claim. In addition, prosecution
4 history estoppel prevents LMA from recapturing what it gave up during prosecution of the patent
5 application in order to obtain allowance.

6 For these reasons and those set out below, partial summary judgment of non-infringement
7 of the remaining AuraFlex™ product should be granted as to claims 3 and 4 of the ‘100 patent.

8 **III. BACKGROUND**

9 **A. The ‘100 Patent**

10 The Court is already familiar with the sole remaining patent-in-suit, the ‘100 patent, having
11 construed its terms on March 17, 2009 [Dkt. 171], and having granted partial summary judgment as
12 to the other accused Ambu devices by order dated June 25, 2009. Dkt. 224. As the Court is aware,
13 the laryngeal mask airway device was invented well prior to the application filing date of the ‘100
14 patent, which claims but a simple improvement to existing devices – a rib running lengthwise at the
15 distal tip of the cuff, helping reinforce the cuff against fold-over.

16 As shown in Ambu’s concurrent motions for summary judgment of invalidity, by the time
17 the application was filed that led to the issuance of the ‘100 patent, numerous other patents had
18 issued or had been filed on improvements to the laryngeal mask, including several that dealt with
19 the very problem addressed by the ‘100 patent – namely, fold-over of the cuff folding during
20 insertion. *See, e.g.*, Declaration of Dr. Samsum Lampotang in Support of Defendants’ Motion for
21 Partial Summary Judgment of Non-Infringement (“Dr. Lampotang April 14 Decl.”) [Dkt. 184.8],
22 Ex. J [EP 0 732 116 A2], Ex. K [U.S. Patent No. 5,983,897]. In addition, many patent applications
23 on airway devices similar to the laryngeal mask had also been filed. *See, e.g.*, Dr. Lampotang April
24 14 Decl. [Dkt. 184.8], Ex. L [U.S. Patent No. 5,791,341], Ex. M [U.S. Patent No. 5,653,229], Ex. N
25 [U.S. Patent No. 5,865,176].

26 The laryngeal mask of the ‘100 patent has four components: (1) “a flexible airway tube,”
27 (2) “a mask attached to one end of the airway tube,” (3) “an inflatable cuff which surrounds the
28 hollow interior of the mask into which the airway tube opens,” and (4) “a reinforcing rib

incorporated into the distal end of the inflatable cuff.” Dr. Lampotang April 14 Decl. [Dkt. 184.8], Ex. E [‘100 patent, col. 1, lines 57-63]. At issue in this motion is the fourth element, which is expressed in claims 3 and 4, respectively, as a “distal rib” and “longitudinal distal rib.”

On March 17, 2009, the Court issued its Order construing these and other disputed claim terms. The Court construed the term “distal rib” as “a narrow stiffener or reinforcement.” *Id.* at 11. In light of the specification and drawings, as well as the general understanding of a “rib,” the Court held that the “distal rib” must be narrow, and not just slightly smaller than the portion of the cuff it reinforces:

In all of the drawings, the “distal rib” is portrayed as a narrow thickening of the cuff. The specification also describes the “distal rib” as “elongate,” (*id.*, col. 6, lines 9-10), which further supports a finding that the ‘distal rib’ must be narrow. Although Plaintiffs’ proposed construction would allow for a narrow “distal rib,” it would not impose a narrowness requirement. Indeed, according to Plaintiffs’ proposed construction, a stiffener that is only slightly smaller than the portion of the cuff being stiffened would qualify as a “distal rib.” Such a construction is inconsistent with the specification and the drawings, and the general understanding of a “rib.” Therefore, the Court rejects Plaintiffs’ proposed construction.

Id. at 10.

B. Ambu’s AuraFlex™

LMA accuses Ambu of infringing claim 3 and 4 of the ‘100 patent by selling, *inter alia*, a laryngeal mask airway device distributed under the trade named AuraFlex™. *See* Dr. Lampotang April 14 Decl. [Dkt. 184.8], Ex. O [LMA’s Patent L.R. 3.1 and 3.2 Disclosure of Asserted Claims, Final Infringement Contentions, and Identification of Document Accompanying Disclosure]. The AuraFlex™ is specially designed for head and neck surgeries; it has a long, wire-reinforced and flexible tube that allows positioning the tube away from the surgical field without a loss of seal. As can be seen below, rather than have a narrow or longitudinal stiffener, the accused AuraFlex™ has a cuff stiffener adopting a broad “V” shape that is slightly smaller than the portion of the cuff being reinforced (*see* image below). *Id.* at ¶ 59. The “V” shape has a rounded, semi-elliptical outline.

Id.



IV. ARGUMENT

A. Legal Standards

There are two steps to determining if there is infringement: (1) construing the meaning and scope of the asserted claim, and (2) determining whether the accused product infringes the properly construed claim. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). The Court has already construed the claim terms. What remains is to compare the construed terms to the accused AuraFlex™ and issue a ruling as a matter of law, since there can be no genuine dispute as to the shape of its stiffener.

An accused product does not infringe unless it contains each and every limitation of the claim, either literally or by an equivalent. *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). As such, the lack of a single claim limitation – here, the “distal rib” and “longitudinal distal rib” elements – means non-infringement. A court may grant summary judgment of non-infringement “when, upon construction of the claims and with all reasonable factual inferences drawn in favor of the non-movant, it is apparent that only one conclusion as to infringement could be reached by a reasonable jury.” *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 540 (Fed. Cir. 1998). “Where the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment.” *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n.8 (1997). Furthermore, “if prosecution history estoppel would apply or if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the

1 court, as there would be no further *material* issue for the jury to resolve.” *Id.*

2 **B. Ambu Is Entitled to Summary Judgment of Non-Infringement of Claims 3**
3 **and 4 on the AuraFlex™**

4 Under the Court’s claim constructions, no reasonable jury could find that the accused
5 AuraFlex™ infringes asserted claims 3 and 4 of the ‘100 patent. The broad, V-shaped stiffener of
6 the AuraFlex™ does not meet the “distal rib” limitation or the “longitudinal distal rib” limitation,
7 either literally or under the doctrine of equivalents.

8 **1. The AuraFlex™ Does Not Literally Infringe Claims 3 and 4 Because**
9 **None of Them Has a “Distal Rib” or “Longitudinal Distal Rib”**

10 Both claims 3 and 4 depend from claim 1 and include a “distal rib” limitation. Claim 3
11 recites: “A device according to claim 1, the portion of the posterior portion of the wall forming a
12 distal rib.” Dr. Lampotang April 14 Decl. (Dkt. 184.8), Ex. E [‘100 patent, col. 10, lines 30-31].
13 Claim 4 recites: “A device according to claim 1, the portion of the posterior portion of the wall
14 forming a longitudinal distal rib for longitudinal supporting a distal region of the cuff.” *Id.* at col.
15 10, lines 32-34.

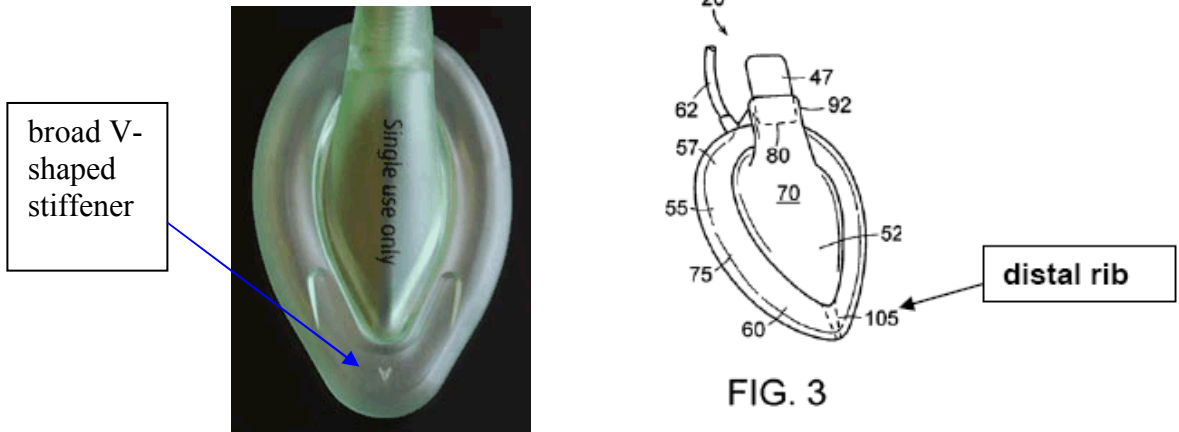
16 The Court construed the term “distal rib” in claim 3 as “a narrow stiffener or reinforcement”
17 and the term “longitudinal distal rib” in claim 4 as “a distal rib running lengthwise.” Order at 11.
18 During claim construction, the parties disputed the meaning of the term “distal rib,” with the Court
19 holding that the “distal rib” “must be narrow.” The Court thus construed the term “distal rib” in
20 claim 3 as “a narrow stiffener or reinforcement” and the term “longitudinal distal rib” in claim 4 as
21 “a distal rib running lengthwise.” *Id.* The Court expressly rejected LMA’s proposed construction
22 that attempted to read the “distal rib” limitation out of claims 3 and 4:

23 Indeed, according to Plaintiffs’ proposed construction, a stiffener that is only
24 slightly smaller than the portion of the cuff being stiffened would qualify as a
25 “distal rib.” Such a construction is inconsistent with the specification and the
26 drawings, and the general understanding of a “rib.” Therefore, the Court
27 rejects Plaintiffs’ proposed construction.

28 *Id.* at 10.

By rejecting LMA’s proposed construction of the term “distal rib,” the Court has foreclosed

LMA's sole theory of literal infringement of claims 3 and 4. The accused Ambu devices have a broad, V-shaped cuff stiffener that is only slightly smaller than the portion of the cuff being stiffened. See images below comparing the accused cuff stiffener (left) with the claimed "distal rib" (right).



To determine whether a cuff stiffener is "narrow," the patent specification teaches that the width of the cuff stiffener should be compared to the width of the cuff. See Lampotang Decl. ¶ 65. As shown above, Ambu's cuff stiffener is not narrow when compared to the width of the cuff it reinforces.

In order to reach the conclusion that Ambu's cuff stiffener is narrow, LMA's expert, Dr. Dilhan Kalyon, opines that any cuff stiffener that is smaller than the cuff it stiffens is narrow. Lampotang Decl. ¶¶ 60-61. Under Kalyon's definition of "narrow" the only reinforcement that would not infringe is one exactly the same size and proportion of the mask itself (or larger than the mask itself). This, effectively, renders the "narrow" requirement meaningless because Dr. Kalyon is essentially opining that *any* reinforcement infringes. The Court already rejected this interpretation as a matter of law in its claims construction. Dr. Kalyon's disagreement with that construction cannot create any genuine issue of fact.

"Narrow" is not synonymous with "smaller than." Indeed, the Court already rejected LMA's proposed "smaller than" construction of "distal rib." Order at 10. Narrow can mean "of slender width"; the opposite of narrow is "wide." See Lampotang Decl. ¶ 61. The opposite of

1 narrow is also “broad.” Woo Decl. Ex. M [Dictionary Definition]. Thus, the Court’s claim
2 construction means that some cuff stiffeners – wide or broad cuff stiffeners – do not infringe
3 Claims 3 or 4 of the ‘100 patent.

4 Dr. Kalyon also opines that Ambu’s cuff stiffener is narrow by comparing the width of the
5 stiffener to aspects of the AuraFlex other than the width of the cuff it stiffens. *See* Lampotang
6 Decl. ¶¶ 60-61. Those measurements of narrowness are not supported by the patent specification.

7 The cuff stiffener in the accused products adopts a broad “V” shape that has a rounded,
8 semi-elliptical outline only slightly smaller than the portion of the cuff being reinforced. *See*
9 Lampotang Decl. ¶ 59. As such, the accused cuff stiffener falls squarely outside the scope of the
10 “distal rib” limitation, and the AuraFlex does not infringe claims 3 or 4.

11 **2. The AuraFlex™ Also Does Not Infringe Claim 4 of the ‘100 Patent**
12 **Because It Does Not Meet the “Longitudinal Distal Rib” Limitation**

13 The Court construed the term, “longitudinal distal rib,” as a “distal rib running
14 lengthwise.” Thus, claim 4 requires that the “narrow stiffener” (i.e. the “distal rib”) must run
15 lengthwise (i.e. in the direction of proximal to distal (or vice-versa)). As shown below, the broad,
16 V-shaped stiffener of the AuraFlex™, in addition to not being “narrow,” runs widthwise/laterally,
17 not lengthwise, and thus does not infringe claim 4 as a matter of law for this additional reason.

18 **3. The Accused Products Do Not Meet the “Distal Rib” or “Longitudinal**
19 **Distal Rib” Limitations under the Doctrine of Equivalents**

20 LMA cannot, as a matter of law, resort to the doctrine of equivalents in order to find present
21 the missing “distal rib” limitation. As explained below, LMA is precluded from broadening the
22 scope of the limitation for at least two reasons. First, finding the distal rib and longitudinal distal
23 rib limitations present by equivalence as LMA suggests would vitiate those limitations in violation
24 of the all-elements rule. Second, the equivalence urged by LMA is unavailable by reason of
25 prosecution history estoppel.
26
27
28

a. **The Doctrine of Equivalents Cannot Be Applied to Vitate the “Distal Rib” or “Longitudinal Distal Rib” Limitations**

“[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.” *Warner-Jenkinson*, 520 U.S. at 29. An element of an accused product is not equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation. *Id.* Vitiating is a question of law appropriate for summary judgment. *Id.* at 39 n.8 (“[I]f a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further *material* issue for the jury to resolve.”). The principle of vitiating, if applicable, precludes the court from reaching factual inquiries under the doctrine of equivalents. *See SciMed Life Sys. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001) (“A particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied.”).

An example of clear exclusion is where the accused product has a physical characteristic that is the exact opposite of what is required by a claim limitation. *See, e.g., Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) (“To hold that ‘unmounted’ is equivalent to ‘mounted’ would effectively read the ‘mounted on’ limitation out of the patent.”); *SciMed Life*, 242 F.3d at 1347 (“[I]f a patent states the claimed device must be ‘non-metallic,’ the patentee cannot assert that the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device.”); *Sage Prods., Inc. v. Devon Indus.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997) (holding that a slot in the interior of a container cannot be equivalent to one “at the top of the container”).

Furthermore, the vitiating principle limits the doctrine of equivalents with equal force even where a claim limitation at issue is not expressly recited in the claim, but is required in light of the specification. *See Novartis Pharms. Corp. v. Eon Labs Mfg.*, 363 F.3d 1306, 1310-12 (Fed. Cir. 2004). In *Eon Labs*, the Court narrowly construed the term “hydrosol” to mean medical products prepared outside of the body, because the specification repeatedly describes the claimed hydrosol as a pharmaceutical composition but “makes no mention of the term in any other context.” *Id.* at

1310. Having construed the term “hydrosol” in that manner, the Court affirmed a summary judgment of non-infringement under the doctrine of equivalents, holding that “[t]o extend the scope of the claims at issue to encompass a dispersion formed inside the stomach would necessarily read the ‘hydrosol’ limitation out of those claims.” *Id.* at 1312 (emphasis added).

Indeed, the Federal Circuit has routinely upheld summary judgment of non-infringement under circumstances analogous to *Eon Labs*. See, e.g., *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1339 (Fed. Cir. 2004) (“lipophilic component” construed as containing at least a non-surfactant cannot be equivalent to a chemical composition made entirely of surfactants); *SciMed*, 242 F.3d at 1345-47 (“catheters” construed to mean catheters with coaxial lumens cannot be equivalent to catheters with side-by-side lumens); *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1305 (Fed. Cir. 2001) (“oxide coating” defined to primarily comprise binary compounds containing only oxygen and a metal cation cannot be equivalent to $AlO(OH)$ or $Al(OH)_3$, which contains an additional element, hydrogen); *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996) (claim construed to require at least three string offset distances in a racket cannot be equivalent to a racket with two offset distances).

Here, the broad, V-shaped stiffener running widthwise/laterally in the AuraFlex™ accused product is so broad that it is only slightly smaller than the portion of the cuff it stiffens, and as such, is the opposite of the “distal rib” and “longitudinal distal rib” limitations as construed by the Court. See Order at 10. A broad stiffener cannot be “narrow,” and one running widthwise/laterally cannot at the same time be “lengthwise.” To extend the “distal rib” limitation to cover the accused products will impermissibly read out the narrowness and lengthwise characteristics of the limitations as construed by the Court.

b. Prosecution History Estoppel Precludes the Doctrine of Equivalents

In addition, prosecution history estoppel precludes application of the doctrine of equivalents to the “distal rib” and “longitudinal distal rib” limitations. Prosecution history estoppel bars a patentee from recapturing what was disclaimed during prosecution of the patent application as a matter of law. See *Warner-Jenkinson*, 520 U.S. at 30. Clear assertions made during prosecution in

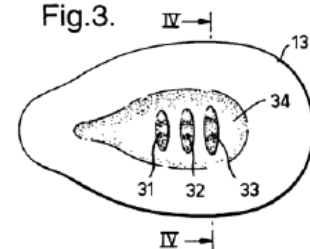
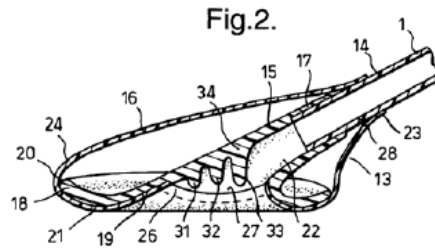
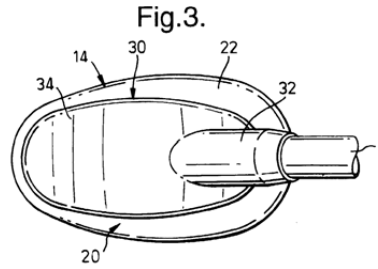
support of patentability, whether or not required to secure allowance, may create an estoppel. *See Pods., Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007).

Furthermore, “once an argument is made regarding a claim term so as to create an estoppel, the estoppel will apply to that term in other claims.” *Id.* (citation omitted). Prosecution history estoppel also applies to identical claim language appearing in a closely related application. *See Desper Prods., Inc. v. QSound Labs., Inc.*, 157 F.3d 1325, 1339 n.6 (Fed. Cir. 1998) (holding that prosecution history estoppel “applies with equal force” to identical claim language appearing in a divisional application); *Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co.*, 66 F.3d 285, 292 (Fed. Cir. 1995) (“[E]stoppel is not avoided by failing to respond to a rejection and instead meeting the substance of the rejection by filing a narrower continuing application.”).

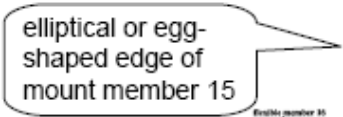
Here, the applicant surrendered equivalents to the “distal rib” limitation by his unmistakable assertions made during prosecution to overcome prior art. During prosecution when pending claims all contained the “distal rib” limitation, the examiner issued an obviousness rejection under 35 U.S.C. § 103(a) over European Patent Application EP 0 732 116 A2 (“Pagan ‘116”) in view of U.S. Patent No. 6,240,922 (“Pagan ‘922.”). Declaration of Darryl M. Woo in Support of Defendants’ Motion for Partial Summary Judgment of Non-Infringement (“Woo April 14 Decl.”) [Dkt. 184.22], Ex. AA [‘100 Patent File History, Oct. 19, 2005 Office Action at 3]. Specifically, the examiner explained that:

The difference between Pagan ‘116 is that the distal rib is not clearly defined. However *Pagan ‘922 clearly shows a distal rib* thereby providing support (at 20; note also Figs. 3[, 5, 7). It would have been obvious to one of ordinary skill in the art to modify the backplate of Pagan ‘116 to employ a longitudinal distal rib doing so [sic] *would* provide support for the cuff including the rib taught by Pagan ‘922.

Id. (emphasis added). The masks of Pagan ‘116 (top) and Pagan ‘922 (bottom) are shown below.



Instead of responding to the rejection in the original application, the applicant filed a continuation application, which ultimately issued as U.S. Patent No. 7,493,901 (“the ‘901 patent”), to continue prosecuting the rejected claims. *See* Woo April 14 Decl. (Dkt. 184.22), Ex. BB [‘901 Patent File History, April 26, 2006 Preliminary Amendment at 2]. Meanwhile, the applicant drafted a new set of claims for the original application. *See* Woo April 14 Decl. [Dkt. 184.22], Ex. CC [‘100 Patent File History, April 24, 2006 Amendment at 2-3]. In the continuation application, the applicant distinguished the prior art Pagan ‘922 on the basis of the size and shape of the “distal rib.” *See* Woo April 14 Decl. [Dkt. 184.22], Ex. BB [‘901 Patent File History, April 26, 2006 Preliminary Amendment at 10]. The applicant argued that Pagan ‘922 does not teach or suggest a distal rib because the corresponding structure has a “rounded profile” when viewed from above. *See id.* Moreover, he argued that the specification of Pagan ‘922 refers to the corresponding structure as having an “inverted dish shape with a generally elliptical or egg-shaped outline,” and that such an outline is not consistent with a “distal rib.” *See id.* Reproduced below are “explanatory drawings” submitted by the applicant to illustrate what an “elliptical or egg-shaped outline” looks like. Woo April 14 Decl. [Dkt. 184.22], Ex. DD.



C. The Doctrine of Ensnarement Also Precludes the Doctrine of Equivalents

1 Lampotang Decl. at ¶ 75. Such a result is barred by the doctrine of ensnarement, and therefore the
2 doctrine of equivalents cannot be used to capture Ambu's V-shaped reinforcement.

3 **V. CONCLUSION**

4 For the foregoing reasons, Ambu's motion for partial summary judgment of non-
5 infringement on claims 3 and 4 with respect to the accused Ambu AuraFlex™ device should be
6 granted.

7
8 DATED: August 14, 2009

FENWICK & WEST LLP

9 By: /s/ *Darryl M. Woo*

10 Darryl M. Woo

11 Attorneys for Defendants and Counterclaimants

12 AMBU A/S, AMBU INC., AND AMBU LTD.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule 5.2 on August 14, 2009.

By: /s/ Darryl M. Woo

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